UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL 2804
	Case No. 17-md-2804
This document relates to:	Hon. Dan Aaron Polster
Track One Cases	

PLAINTIFFS' *DAUBERT* ROADMAP BRIEF

July 31, 2019

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

Cases

Statutes, Rules, and Regulations

Other Authorities

INTRODUCTION

In fourteen *Daubert* motions challenging eighteen (out of a total of nineteen) experts disclosed by Plaintiffs Summit County and Cuyahoga County,[1] Defendants ignore the mandate of the Supreme Court and the Sixth Circuit regarding the admissibility of expert testimony. Exclusion of expert testimony is the exception, rather than the rule, and is intended to weed out "junk science" and unreliable expert opinion that may mislead a jury. Plaintiffs' experts, by contrast, are highly-credentialed, even lauded, professionals in their respective fields. Their expert reports, and the opinions set forth in them, reflect the application of the very same techniques they have used in either their published, academic work, their work on behalf of governmental entities, or in the practice of their professions.

The opinions these experts propose to offer at trial provide important information to aid the fact-finder on issues ranging from the science of addiction and addiction medicine, the effectiveness of Defendants' marketing, the failure of the Defendants to maintain effective controls against diversion, the effects of the failure to maintain those controls, how Defendants' misconduct caused harms in the Plaintiff counties (and throughout the United States), quantification of the costs of Defendants' conduct, as well as what is required to address the opioid epidemic and how much it will cost to do so. Many of these opinions involve the analysis of large quantities of data through application of standard statistical techniques that reveal patterns and connections explaining how the conduct of the Defendants changed prescribing practices, increased opioid supply throughout the country, and created the opioid crisis. This kind of large-scale analysis – seeing the crisis as a whole – relies on the work of experts to make sense of the wealth of data available about how the opioid epidemic came about. Without it, the fact-finder would be left with anecdotal evidence that fails to capture the magnitude of what has occurred.

Defendants, of course, disagree with the conclusions of Plaintiffs' experts, as is their right.

[1] Defendants have not sought to exclude the testimony of Plaintiffs' medical history expert, Professor David Courtwright.

They have identified, and provided reports for, some 84 experts of their own, many, if not most, in similar fields to Plaintiffs' experts, performing similar analyses, reaching in many instances very different conclusions.[2] But Defendants' disagreement with Plaintiffs' experts provides no basis to exclude the testimony of any of these experts. Defendants' motions rest on a fundamental misunderstanding of the *Daubert* inquiry and, in many instances, mischaracterizations of the expert testimony they seek to exclude.

Plaintiffs are separately responding to each of the Defendants' *Daubert* challenges, providing individualized explanations and analysis of the work of each challenged expert and showing how and why Defendants' challenges are without merit. Plaintiffs here respond to Defendants' "roadmap" brief, which purports to set forth the legal standards applicable to their motions and to provide the Court an overview of Plaintiffs' experts and their opinions. But Defendants' discussion of *Daubert* standards is incomplete and provides a misleading picture of the state of the law and the nature of the inquiry permitted by the Supreme Court and the Sixth Circuit. Plaintiffs here provide the Court with several *Daubert* concepts omitted from the Defendants' brief, and provide the framework for assessing all of the Defendants' motions to exclude expert testimony.

Defendants' overview of Plaintiffs' experts is also incomplete, and indeed, misleading. Defendants attempt to group Plaintiffs' experts by the elements of Plaintiffs' legal claims to which Defendants believe each expert's opinion pertains. But the experts' fields of expertise do not align neatly with the elements of Plaintiffs' claims, and Defendants' chart obscures, rather than clarifies, how the opinions of the various experts fit together. Defendants also summarize their criticisms of each of Plaintiffs' experts, but fail to provide any information about the qualifications of the experts they discuss and provide only incomplete and misleading descriptions of the opinions they proceed

[2] Plaintiffs have not sought exclusion of any of these experts and will instead rely on "vigorous cross-examination [and] presentation of contrary evidence," as the Supreme Court has instructed. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 596 (1993),

to criticize. In response, Plaintiffs here offer a "roadmap" to their own experts, providing the Court an overview of each expert's qualifications, field and opinions, and showing how the opinions of these experts relate to each other and fit together, and thus how they will assist the trier of fact in understanding the complex evidence in this case.

I. LEGAL STANDARDS REGARDING *DAUBERT* MOTIONS

A. *Daubert* and Fed. R. Evid. 702

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993),the Supreme Court provides an analytical framework for determining whether expert testimony is admissible under Rule 702 of the Federal Rules of Evidence. Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Thus, pursuant to Rule 702, the district court functions as a gatekeeper, ensuring that the expert is qualified, and his or her testimony is both relevant and the product of reliable methods. *Daubert*, 509 U.S. at 589, 590-91, 592-93; *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149 (1999).

In *Daubert*, the Supreme Court provided a list of four non-exhaustive factors that a court may use in making its gatekeeping determination of reliability: (1) "whether a theory or technique … can be (and has been) tested," (2) "whether the theory or technique has been subjected to peer review and publication," (3) whether, "in the case of a particular scientific technique," there is a high "known or potential rate of error" and there are "standards controlling the technique's operation," and (4) whether the theory or technique enjoys "general acceptance" within a "relevant scientific community." 509 U.S. at 593-94. However, the *Daubert* factors are not definitive or exhaustive. *See Broussard v. State*, 523 F.3d 618, 631 (5th Cir. 2008) (data from space center and eyewitnesses relied upon to form opinion was sufficiently reliable and expert opinion admissible despite fact "his work

had not been peer reviewed and he did not know of others who had used his methods"); *see also In re Vioxx Prod. Liab. Litig.*, No. 05- cv-4046, 2006 WL 6624015, at *4 (E.D. La. Feb. 3, 2006) ("Whether some or all of [the *Daubert*] factors apply in a particular case depends on the facts, the expert's particular expertise, and the subject of his testimony."), *citing Kumho Tire*, 526 U.S. at 138. Instead, "the test of admissibility under Rule 702 is a flexible one that must be tailored to the facts of each case." *Kipps v. Caillier*, 197 F.3d 765, 769 n.6 (5th Cir. 1999) (internal quotation marks and citations omitted).

B. Defendants Failed to Discuss Several Important *Daubert* Concepts

Several concepts related to *Daubert* law were not mentioned in Defendant's memorandum in support of *Daubert* motions. These include: (1) the court's gatekeeping role is not intended to replace the jury in the adversary system; (2) the *Daubert* inquiry is focused on methodology, not conclusions; (3) facts on which an expert bases his or her opinion need not be in the record; (4) the rejection of expert testimony is the exception rather than the rule; (5) expert testimony that synthesizes voluminous and technical materials may assist the trier of fact; and (6) statistical analysis may assist the trier of fact and is not excluded merely because it assesses data other than directly involved in the case; (7) the district court has broad discretion in determining the admissibility of expert testimony.

1. The Daubert Inquiry Is Not Intended to Replace the Adversary System

Defendant's memorandum fails to acknowledge that "the trial court's role as gatekeeper [under *Daubert*] is not intended to serve as a replacement for the adversary system." *Burgett v. Troy-Bilt LLC*, 579 F. App'x 372, 376 (6th Cir. 2014), *citing* Fed. R. Evid. 702 advisory comm. Note (2000); *see also U.S. v. 14.38 Acres of Land, More or Less Situated in Leflore County*, 80 F.3d 1074, 1078 (5th Cir. 1996). *Daubert* makes clear that the appropriate means of attacking admissible, albeit shaky, evidence is through vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof. 509 U.S. at 596*; see also Best v. Lowe's Home Centers, Inc.*, 563 F.3d 171, 180 (6th Cir. 2009). For example, though an expert's proponent must establish that the proffered expert is qualified to testify by virtue of his or her knowledge, skill, experience, training or education, a lack of

specialization should generally go to the weight of the evidence, not its admissibility. *See First Tennessee Bank Nat. Ass'n v. Barreto*, 268 F.3d 319, 333 (6th Cir. 2001) (lack of familiarity with some aspects of the subject matter "merely affected the weight and credibility of his testimony, not its admissibility"); *Laski v. Bellwood*, 132 F.3d 33 (6th Cir. 1997) (district court abused discretion excluding testimony of causation experts who were "only" medical specialists and not experts in biomechanics or accident reconstruction because "[r]equiring such specialization thwarts the goals and purposes of the Federal Rules").

Whether expert opinions are admissible under Rule 702 is, moreover, a "preliminary question" governed by Fed. R. Evid. 104(a). "Rule 104(a) requires the judge to conduct preliminary fact-finding and to make a 'preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.'" *Moore v. Ashland Chemical Inc.*, 151 F.3d 269, 276 (5th Cir. 1998), *citing Daubert*, 509 U.S. at 592-93. The proponent of the testimony need only show by a preponderance of the evidence that the opinions are admissible. *Ullman v. Auto-Owners Mut. Ins. Co.*, 502 F. Supp. 2d 737, 742 (S.D. Ohio 2007), *citing In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir.1994).

2. The Daubert Inquiry Is Focused on the Expert's Methodology, Not on His or Her Conclusions

The Supreme Court in *Daubert* was careful to emphasize that the expert's methodology, not her conclusion, is the subject of the Rule 702 inquiry. Noting that the "overarching subject" of the Rule 702 inquiry "is the scientific validity and thus the evidentiary relevance and reliability of the principles that underlie a proposed submission," 509 U.S. at 594-95, the Court went on to hold that "[t]he focus, of course, must be solely on principles and methodology, not on the conclusions that they generate."." *Id.* at 595. The Sixth Circuit has repeatedly echoed this caution. *See, e.g., Decker v. GE Healthcare Inc.*, 770 F.3d 378, 391 (6th Cir. 2014); *Best*, 563 F.3d at 177; *U.S. v. Demjanjuk*, 367 F.3d 623 (6th Cir. 2004) (where methodology was neither original nor controversial, district court properly

admitted expert testimony).

Thus, the role of the district court is to evaluate whether the methodology used by the expert is reliable, *i.e.*, whether, when correctly employed, that methodology leads to testimony helpful to the trier in fact. *See Daubert*, 509 U.S. at 595. Nothing in Rule 702 or *Daubert* and its progeny, or in the rulings of the Sixth Circuit permits this Court to subject an expert's conclusions, as opposed to his methodology, to the *Daubert* analysis. The proponent of expert testimony does not need to prove that the expert's testimony is correct. *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 531 (6th Cir. 2008) (whether expert's opinion is accurate goes to weight of the evidence, not to its admissibility, and "the district court appropriately passed the torch to the jury to make this determination").

Moreover, "[a]dmissibility under Rule 702 does not require perfect methodology. Rather, the expert must employ in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Best*, 563 F.3d at 181. Indeed, in *Best*, the Sixth Circuit held that where the expert's overall methodology was sound, "[a]ny weaknesses in his methodology will affect the weight that his opinion is given at trial, but not its threshold admissibility." 563 F.3d at 182; *see also Paoli R.R. Yard.*, 35 F.3d at 744 ("The grounds for the expert's opinion merely have to be good, they do not have to be perfect. The judge might think that there are good grounds for an expert's conclusion even if the judge thinks that there are better grounds for some alternative conclusion, and even if the judge thinks that a scientist's methodology has some flaws such that if they had been corrected, the scientist would have reached a different result.").

3. Facts on Which an Expert Bases His or Her Opinion Need Not Be in the Record

The Sixth Circuit has held that the facts on which the expert bases his opinion need not be in the record. *In re Southeastern Milk Antitrust Litig.*, 739 F.3d 262, 280 (6th Cir. 2014). The Court agreed that an expert report should be excluded where it was based on "assumptions and estimates as inputs that were implausible and inconsistent with record evidence," *id.*, and that the facts on which an opinion is based "can be undependable for numerous reasons, including actual information that is of

poor quality, and contradictory facts present in the record." *Id.* But where the expert relies on facts from government studies and academic publications and other similarly reliable sources, his opinion should not be excluded merely because those facts are not independently in the record. *Id.*at 280-81. As the Court explained, "expert reports must be based on proper facts, but each of those facts does not have to occupy an independent part of the record for an expert to be able to use them when crafting an opinion." *Id.* at 281. *See also V & M Star Steel v. Centimark Corp.*, 678 F.3d 459, 467 (6th Cir. 2012) (expert's opinion about the effect of gravity if "the bands [around a bundle of roofing panels] are cut" was admissible despite the absence of evidence that the bands had been cut, because his opinion would assist the jury in understanding the force of gravity on the roofing panels).

4. Rejection of Expert Testimony Is the Exception Rather than the Rule

Daubert and Rule 702 are not intended to provide an automatic challenge to the testimony of every expert. *See Kumho Tire*, 526 U.S. at 150-51. Rather, "the rejection of expert testimony [under *Daubert*] is the exception rather than the rule." *U.S. ex rel. Tennessee Valley Auth. v. 1.72 Acres of Land In Tennessee*, 821 F.3d 742, 749 (6th Cir. 2016); *Scrap Metal Antitrust Litig.*, 527 F.3d at 530, *quoting* Fed. R. Evid. 702 advisory committee note (2000). Thus, "any doubts [about the admissibility of expert testimony] should be resolved in favor of admissibility." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 709 (S.D. Ohio 2016), *citing Daubert*, 509 U.S. at 594.

5. Experts May Assist the Trier of Fact in Understanding and Synthesizing Voluminous Materials

Summary and narrative testimony may be admissible to assist the trier of fact in understanding and synthesizing voluminous evidence. As another MDL judge has observed, "the Court has broad discretion over the mode and order of examining witnesses and presenting evidence and may allow testimony in narrative form at trial if the Court finds it would be helpful to the jury." *In re Yasmin and YAZ (Drospirenone) Marketing, Sales Practices, and Prods. Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, 2011 WL 6302287 at * 26 (S.D. Ill. Dec. 16, 2011). While an expert must do more than simply

construct a factual narrative based on record evidence, an expert can testify as to the facts relied upon in forming his opinions so long as he does not "merely parrot back uncomplicated corporate documents containing information within the ken of a jury," but rather applies his expertise to the material he discusses. *Du Pont C-8 Litig.*, 345 F. Supp. 3d at 926–27. Indeed, in complex litigation, involving voluminous evidence and multiple parties, and spanning many years, the use of synthesis expert testimony is likely to be particularly helpful to the fact-finder. *See In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, 2017 WL 1836443, at *15 (N.D. Ill. May 8, 2017) (rejecting argument that expert was merely regurgitating evidence, court held that "to the extent [the expert] is summarizing voluminous records and materials, as appears to be the case, this aspect of his testimony is properly admitted under Federal Rule of Evidence 1006 as well as Rule 702 in the sense that he is identifying what he, given his background and expertise, considers to be the most salient aspects of those voluminous materials."); *In re Laurel Valley Oil Co.*, No. 05-64330, 2015 WL 4555579, at *6 (Bankr. N.D. Ohio July 28, 2015) (expert testimony including recitation of facts admissible because it "does not consist solely of factual regurgitation or 'common sense' observations, but instead combines expert knowledge with a factual underpinning to arrive at valid expert testimony").

Moreover, under Rule 26, Plaintiffs' experts were required to disclose not only their opinions, but also the basis and reasons for those opinions. *See* Fed. R. Civ. P. 26(a)(2)(B). Their reports, of necessity, contain detailed recitations of the facts and information underlying their opinions. How much of this information they should be permitted to offer at trial is best determined at the time of trial, when the Court can assess the context of their testimony. As the MDL judge in the *Actos* litigation explained:

> [A]an objection to the "narrative" nature of testimony is an objection as to the form of a question or the foundation or responsiveness of a witness' answer, and is properly asserted at trial. Furthermore, it is not a proper objection to an expert report, that, itself, will not be placed into evidence, nor to a *Daubert* challenge. . . . Nor is it a proper

> objection to infer a report contains too much information as Defendants' argument suggests.

In re Actos (Pioglitazone) Prod. Liab. Litig., No. 12-CV-00064, 2014 WL 120973, at *14 (W.D. La. Jan. 10, 2014); *see also Testosterone Replacement Therapy*, 2017 WL 1836443, at *15 (narrative summary of records may be admissible at trial under Fed. R. Evid. 1006 (summaries to prove content)).

6. Statistical Analysis Is an Appropriate Form of Expert Opinion

In assessing "fit," *i.e.*, whether an expert's testimony will "help the trier of fact to understand the evidence or to determine a fact in issue," Fed. R. Evid. 702(a), the Court must determine whether there is some "connection between the scientific research or test result being offered and the disputed factual issues in the case in which the expert will testify." *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000). An expert's statistical analysis of aggregate rather than solely party-specific evidence does not undermine its relevance or fit. *See*, *e.g.*, *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1046 (2016) ("A representative or statistical sample, like all evidence, is a means to establish or defend against liability. Its permissibility turns . . . on the degree to which the evidence is reliable in proving or disproving the elements of the relevant cause of action."); *In re Neurontin Mktg., Sales Practs., and Prods. Liab. Litig.*, 712 F.3d 21, 42-43 (1st Cir. 2013) ("[C]ourts have long permitted parties to use statistical data to establish causal relationships.").

7. The District Court Has Broad Discretion

A district court's determination of admissibility of expert evidence under *Daubert* is reviewed for abuse of discretion. *U.S. v. Kalymon*, 541 F.3d 624, 636 (6th Cir. 2008); *Brainard v. Am. Skandia Life Assur. Corp.*, 432 F.3d 655, 663 (6th Cir. 2005). District courts also have broad discretion in choosing the method to employ in determining the admissibility of expert testimony; a district court need not hold a *Daubert* hearing if the reliability inquiry can be resolved on paper through the submissions of the parties. *See, e.g., Kumho Tire*, 526 U.S. at 152-53; *Scrap Metal Antitrust Litig.*, 527 F.3d at 532. The court's discretion "is at its zenith during a bench trial." *Kalymon*, 541 F.3d at 636.

II. ROADMAP TO PLAINTIFFS' EXPERTS

In their Roadmap, Defendants assail Plaintiffs' expert witnesses as advocates rather than experts with specialized knowledge or expertise that will assist the trier of fact. *See* Def. Roadmap at 1. (They even put the term "experts" in quotation marks.) In fact, Plaintiffs have assembled a team of world-class, highly-credentialed academics and professionals; included among them are professors at some of the most prestigious universities in the country (indeed, the world) who have made their reputations in the fields in which they now offer expert opinions. Given the scale of the crisis at issue, Plaintiffs believe it is important to provide the Court with the most reliable opinions of the top experts in their respective fields. Many of Plaintiffs' experts conducted research into the opioid epidemic long before they were retained as experts, and in several instances published those conclusions before being retained. These experts were retained because of their unparalleled expertise and knowledge about the opioid crisis, or about the methodologies necessary to carry out their analysis. Even a cursory review of their credentials and opinions demonstrates the baselessness of Defendants' attack on their *bona fides*. Plaintiffs here provide an overview of each of their experts and his or her work, so that the Court may understand how the opinions of Plaintiffs' various experts fit together and judge for itself the extent to which the opinions of these highly qualified individuals will assist the trier of fact.

A. Plaintiffs' Experts on Addiction and the Opioid Crisis: Understanding the True Nature of Opioids, Opioid Addiction, and the Opioid Epidemic

Plaintiffs designated and provided reports for three experts pertaining to the true nature of opioids, opioid addiction and the opioid epidemic: Dr. Anna Lembke, Dr. Mark Schumacher and Dr. Katherine Keyes.[3] Taken together, these experts will help the fact-finder understand how for the vast majority of chronic pain patients, the risks of prescription opioids significantly outweigh any benefits; why the defendants' marketing was misleading; how it fueled the opioid epidemic; how it caused

[3] Defendants have filed two motions that seek to exclude some of Dr. Lembke's opinions (in combination with opinions of other experts), one to exclude the opinions of Dr. Schumacher (in combination with other experts), and three motions to exclude the opinions of Dr. Keyes (in various combinations with other experts).

tremendous harm; and what strategies will be needed to abate the opioid epidemic.

1. Dr. Lembke: Why Defendants' Marketing Was Misleading and How It Fueled the Opioid Epidemic

Dr. Anna Lembke is Associate Professor, Chief of the Addiction Medicine Dual Diagnosis Clinic, Medical Director of Addiction Medicine, and Program Director of the Addiction Medicine Fellowship in the Department of Psychiatry and Behavioral Sciences at Stanford University. She received her medical degree from Stanford, where she also completed a residency in Psychiatry, as well as a Fellowship in Mood Disorders, Department of Psychiatry and Behavioral Sciences. She is board-certified in Psychiatry and Neurology as well as Addiction Medicine. Since 2001 she has taught medical students, residents, and fellows at Stanford on a diversity of topics related to psychiatry, addiction, and pain. For the last 15 years, her clinical practice has included a significant proportion of patients taking prescription opioids for pain relief, for whom such drugs have resulted in misuse, dependence, and addiction. As an integral part of her practice, she works with these patients to develop treatment plans that will address their pain while making appropriate efforts to reduce or eliminate the use of opioids and to treat their opioid addiction. In 2015 she was appointed by Governor Jerry Brown to the Research Advisory Panel of California, and her work on that panel included assessing the safety of clinical trials using controlled substances, including opioids. Since 2015, she has served on the Board of the California Society of Addiction Medicine. In 2016, she became president of the Addiction Medicine Fellowship Directors Association. Since 2016, she has chaired the Addiction Medicine Task Force at Stanford. She is the author of a book on the prescription drug epidemic: *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop* (Johns Hopkins University Press, October 2016), and she has extensively published peer-reviewed articles, chapters, and commentaries, as well as non-peer reviewed articles and research letters, on the diagnosis and treatment of addiction, the treatment of pain, the importance of teaching addiction medicine in medical school, residency, and fellowship, opioid misuse and addiction, risk assessment and mitigation,

patient education, tapering to reduce or end opioid exposure, tolerance, dependence, risks of overdose, opioid drug prescription patterns, efforts to curtail opioid overprescribing, the growing incidence of opioid use disorder, and the management of patients with chronic pain and opioid use disorder. She has testified before the United States House of Representatives on the opioid epidemic and possible means to mitigate harms caused by that epidemic.

Dr. Lembke opines that the defendants made misleading marketing claims to promote opioid sales and prescriptions without reliable scientific evidence and that this marketing was a primary driver in the massive increase in the sale of opioids. She explains why the marketing claims were false, and what the truth is about opioids, dependence, misuse, and addiction. In particular, Dr. Lembke provides extensive evidence that Defendants understated the risks of their products (especially as to addiction and mortality), while overstating the purported benefits (especially as to the treatment of chronic pain). She also explains how the increase in opioid sales that followed Defendants' marketing campaign triggered the prescription opioid epidemic that plagues the United States. She further opines that there is a clear, causal link between prescription opioid exposure and the subsequent use of heroin and other illicit opioids (known as "The Gateway Effect"). Dr. Lembke also explains the ways in which communities have been harmed and the significant investment of resources that will be needed to end the epidemic of opioid addiction, dependence and death.

2. Dr. Schumacher: Pain Medicine and the Standard of Care; the Risk Benefit Analysis

Dr. Mark Schumacher is a Professor and Chief of the Division of Pain Medicine in the Department of Anesthesia and Perioperative Care at the University of California, San Francisco ("UCSF"). He holds a PhD in Physiology and Pharmacology and a medical degree from the University of California, San Diego. Following an internal medicine internship at Cedars Sinai Medical Center, he completed a residency in anesthesiology at UCSF. He has served on the National Academy of Sciences, Engineering, and Medicine Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse – Consensus Report, 2017. He has taught pain management to

medical students, residents and fellows. He co-authored a chapter on "Opioid Analgesics & Antagonists" in Katzung's *Basic and Clinical Pharmacology* (8th – 14th editions). Dr. Schumacher has expertise in opioid and non-opioid strategies in pain control, treats patients with acute pain, chronic pain, and "acute-on-chronic pain," and has worked successfully to introduce multidisciplinary pain care and non-opioid analgesic strategies at UCSF Medical Center.

In his expert report, Dr. Schumacher opines that in the field of pain medicine the standard of care for treating both chronic and acute pain was changed as a result of widespread promotion and marketing of opioids by Manufacturer Defendants that trivialized the risk of addiction and exaggerated the benefits of long-term opioid use. He further opines that those defendants influenced physicians through direct-to-physician marketing, medical education, and industry-sponsored and -funded Key Opinion Leaders to prescribe long-term opioids based on misinformation about the risks and benefits of chronic opioid use. He explains that for the vast majority of chronic pain patients, the risks of prescription opioids significantly outweigh any benefits, and that at most, a small percentage of chronic pain patients achieve meaningful relief from the long-term use of opioids. Indeed, even for those indications for which opioids are effective, such as trauma or post-operative pain, the risks of prescribing opioids are significant such that non-opioid alternatives or multimodal analgesia should be used whenever possible to reduce opioid use. He concludes that the increased prescribing of opioids in the United States caused tremendous harm that would not have occurred but for the actions of the companies that aggressively promoted the use of opioids for a wide array of conditions beyond short-term acute pain, cancer pain from active disease, and end-of-life and hospice care.

3. Dr. Keyes: How the Increase in Opioid Prescriptions Caused the Increase in Opioid Use Disorder and the Strategies Needed to Abate the Epidemic

Dr. Katherine Keyes is an Associate Professor of Epidemiology at Columbia University, specializing in substance use and substance use disorders epidemiology. She holds a Master's degree in Public Health and a Ph.D. in Epidemiology from Columbia. She has published two textbooks on

epidemiological methods, and is well-qualified to assess the literature on opioid-related harm. She has published 225 peer-reviewed articles and book chapters, more than 60 of which are first-authored, and almost 70 of which have been cited over a hundred times. She has published 19 peer-reviewed journal articles on opioid use and related harms (and many more on drug use disorders more generally).

In her expert report, Dr. Keys explains that the medical and non-medical use of opioids is causally associated with the development of opioid use disorder at higher rates than reported by Defendant Manufacturers, and that the rates of opioid use disorder increase with the dose and length of opioid use among medical users. She explains how the dramatic increase in the supply of opioids beginning in the early 1990s directly caused an increase in the incidence and prevalence of opioid use disorder. She also explains how prescription opioid use is also causally related to subsequent heroin/fentanyl use. Dr. Keyes links the higher rates of prescription to the harms suffered by communities like Summit and Cuyahoga Counties, including fatal overdoses, non-fatal overdoses, neonatal abstinence syndrome, and physiological dependence. Finally, she addresses the abatement strategies that will be needed to abate the opioid epidemic, including medication assisted treatment ("MAT"), harm reduction through naloxone availability, and synthetic opioid testing and warning systems.

B. Plaintiffs' SOM Experts: Assessing the Defendants' Failure to Control the Supply Chain for Opioids

Plaintiffs designated and provided reports for four experts pertaining to Defendants' failure to control the supply chain for opioids and to meet their statutory obligations: Dr. Seth Whitelaw, Dr. Craig McCann, James E. Rafalski, and Lacey Keller.[4] These experts provide opinions about suspicious order monitoring ("SOM") programs and analyze data that was available to the Defendants to show what information Defendants had and what their compliance programs would have found

[4] Although Defendants filed separate motions to exclude against each of these four experts, Plaintiffs are responding to the McCann and Rafalski motions together in a single opposition.

had Defendants analyzed this information. Their opinions provide important evidence that Defendants' violations of the Controlled Substances Act ("CSA") were not mere technical violations without consequences. Although Defendants failed to identify suspicious orders in any significant quantities, the opinions of Plaintiffs' SOM experts show that there were tens of thousands of suspicious orders to be discovered if anyone had been looking for them.

1. Dr. Whitelaw: Corporate Compliance

Dr. Seth Whitelaw is a lawyer with specific expertise in corporate compliance in the pharmaceutical industry. He holds J.D., LL.M and S.J.D. degrees, and teaches various aspects of corporate compliance to law students and working professionals, who are enrolled in Mitchell Hamline School of Law's Healthcare Compliance Certificate program. He ran corporate compliance programs at several pharmaceutical companies, and, as a consultant, has assessed the effectiveness of numerous such programs.

Dr. Whitelaw provides information about corporate compliance generally and how suspicious ordering monitoring fits into the overall compliance scheme. He offers opinions about the industry standards and practices of corporate compliance in the United States and, in particular, in the pharmaceutical industry. Dr. Whitelaw assessed the compliance practices of several of the Defendants (McKesson, Cardinal, AmerisourceBergen, CVS, Walgreens, and Mallinckrodt). In doing so, he used the same methodology he has used over the last 30 years when auditing or investigating compliance issues. He reviewed a wealth of information about the Defendants' programs and evaluated the programs against the compliance standards elaborated in his report. He found systemic failures in each of their compliance programs, which had significant adverse effects on their ability to properly conduct suspicious order monitoring for opioids.

2. Mr. Rafalski and Dr. McCann: Assessing the Manufacturers' and Distributors' Suspicious Order Monitoring Systems Using Relevant Data Sources

James Rafalski and Dr. Craig McCann, in separate, but inter-related reports, analyze ARCOS

and other data and assesses the failure of the Defendants to maintain effective controls against diversion. Mr. Rafalski was a DEA Diversion Investigator for more than a dozen years and served, during that time, as a DEA Instructor for multiple DEA training courses. Dr. McCann has a Ph.D. in Economics from the University of California at Los Angeles; his education included extensive training in mathematics, statistics and econometrics. He taught economics at various universities around the country, worked for the Securities and Exchange Commission (where he was a senior financial economist in the Office of Economic Analysis), and was a Managing Director at the consulting firm KPMG LLP. He has published numerous articles about financial markets. Dr. McCann has provided three expert reports in this litigation, an original report ("McCann Report"), a first supplemental report[5], and a second supplemental report.

Based on his experience at the DEA, Mr. Rafalski offers the opinion that there was a systematic, prolonged failure over many years by the defendant manufacturers and distributors to maintain effective controls against diversion of legitimate opioid prescriptions into the illicit market and that this systematic failure was a substantial cause of the opioid epidemic in the United States and specifically in Cuyahoga County and Summit County. Mr. Rafalski is also able to explain to the fact-finder the relevant regulatory duties under the CSA, as well as the sources of information (including ARCOS data) available to the DEA. His report explains the components of an effective SOM system, as well as the characteristics of the due diligence required before a suspicious order may be shipped. Mr. Rafalski's report makes clear that, although registrants must design their own SOM systems and there is no one single system appropriate in all circumstances, *all* effective systems must include certain components and *all* due diligence programs must include certain characteristics. The report further explains how the failure to maintain an effective SOM program and/or the failure to perform adequate

[5] The first supplemental report provided additional tables that present data used in the original report in a slightly different format and that summarize the electronic data attached to the original report. These supplemental tables and figures do not in any way alter his original conclusions.

due diligence may lead to diversion.

Mr. Rafalski identifies five suspicious order monitoring algorithms, including the methodology set forth in *Masters Pharmaceutical, Inc., v. DEA*, 861 F.3d 206 (D.C. Cir. 2017), as well as four methodologies used by one or more Defendants to identify suspicious orders. Dr. McCann then analyzed various datasets using the algorithms identified by Mr. Rafalski. In his original report, Dr. McCann applied the five algorithms to the ARCOS data produced by the DEA (which Dr. McCann opines are reliable) to determine, for each of four Distributors, how many orders would have been flagged by each algorithm. In his second supplemental report, Dr. McCann processes additional data in order to attribute Distributors' downstream shipments to the Manufacturers who supplied the product the Distributors shipped. He determined that, through a combination of National Drug Codes, ARCOS data, chargeback data, and IQVIA/IMS data, he could trace back through the transactions from Distributors to their customers to the first reported transaction which could plausibly have led to the Distributor's sale. He was then able to attribute the flagged transactions from his original report to particular Manufacturer Defendants. In this way, Dr. McCann provides an analysis from which it is possible to determine which Manufacturers' drugs were included in the orders that the algorithms flagged.

Using Dr. McCann's analysis of the data and the algorithms, Mr. Rafalski assesses the number of oxycodone and hydrocodone orders shipped into Summit County and Cuyahoga County by four distributor defendants that would have been flagged using each of these metrics.[6] The numbers are stark: they show that the *vast majority* of oxycodone and hydrocodone orders would have been flagged as "suspicious" (and thus halted pending due diligence) under *any* of the five metrics. Mr. Rafalski then reviewed the SOM systems actually used by Cardinal, McKesson, ABDC, CVS, Walgreens, Henry

[6] Dr. McCann's analysis of the number of orders that would have been flagged is also relied upon by another of Plaintiffs' experts, Dr. David Cutler, discussed below, in his quantification of the share of prescription opioid shipments resulting in harms to the Bellwether jurisdictions.

Schein, Allergan, Janssen, Mallinckrodt, Purdue Pharma, Endo, and Teva, using internal company documents as well as other materials. He reviewed the various policies each defendant used to identify suspicious orders; the number of orders reported to the DEA for Summit and Cuyahoga Counties; the due diligence, if any, conducted by each defendant; as well as the history of enforcement actions with respect to each. Based on this information, Mr. Rafalski offers opinions about the effectiveness of each of the listed defendants' programs to maintain effective controls against diversion and, in particular, opines that none of the systems he examined satisfied the requirements to maintain such controls. He opines that there was a systematic, prolonged failure over many years by the defendant manufacturers and distributors to maintain effective controls against diversion.

3. Lacey Keller: Using Manufacturer Sales Data and Defendants' Own Metrics to Identify Suspicious Orders

Lacy Keller holds a Master of Economics degree from the New School for Social Research and a Certificate in Data Science from General Assembly. She is the Managing Director for Data-mining & Analytics with Gryphon Strategies, Inc., a leading investigation firm, where she created and directs their data-mining and analytics division. Prior to founding Gryphon's Data-mining & Analytics Division, she founded and directed the Research and Analytics Department for the New York State Office of the Attorney General ("NYAG"), where she served from 2013 to 2017. Her primary role at the NYAG's office was to help the office identify areas for investigation using data. She has worked extensively on issues relevant to opioids. For example, while at the NYAG, she developed and managed the Community Overdose Prevention Program to use data analytics to determine how best to deploy life-saving naloxone across New York State. Chief among the datasets she used was the DEA's ARCOS data.

Using her expertise in the science of data-mining, Keller applied certain industry standard metrics as well as defendants' own SOM compliance metrics to analyze data that was available to Manufacturers and show how using that data for SOM purposes would have identified orders of

unusual size, frequency, or pattern. Using IQVIA Xponent data, which provides data on every opioid prescription filled, tracking the doctor who wrote the prescription and the drug prescribed, Keller was able to identify physicians in Summit and Cuyahoga counties whose prescribing activity would have been flagged by application of defendants' SOM metrics. She was also able to determine the number of prescriptions, dosage units, and morphine milligram equivalents ("MMEs") that those physicians' prescriptions represented. Using other types of data available to Manufacturers, Keller was able to identify pharmacies in Summit and Cuyahoga counties whose buying activity would be flagged by the SOM metrics. She was also able to determine the number of transactions within the dataset that would be flagged, the number of dosage units that those transactions represented and which Manufacturers' sales were associated with the flagged transactions. This data analysis provides a foundation for other experts—and the fact-finder—to draw conclusions about the adequacy of Defendants' suspicious order monitoring and the impact of their failure to report and halt suspicious orders. Keller's analysis also pertains to the question of causation, because, by identifying the suspicious orders that could have been discovered, and linking them to specific diversion points in Summit and Cuyahoga Counties, Keller's analysis demonstrates what would or could have occurred but for Defendants' failure to identify, report, and halt suspicious orders

C. Plaintiffs' Economists: Quantifying Causation, Harm and Damages

Plaintiffs designated and provided reports for four academic economists on the issues of causation, harms, and damages: Professor Meredith Rosenthal, Professor Jonathan Gruber, Professor David Cutler, and Professor Thomas McGuire.[7] The reports are inter-related and together provide important evidence to quantify causation and damages. Together, the reports of the economists show how unlawful marketing caused increased sales of opioids; how increased shipments of opioids caused increased harms in Summit and Cuyahoga County; and how increased harms in those counties caused

[7] Defendants have filed one motion to exclude the opinions of Prof. Rosenthal, one to exclude the opinions of Prof. Cutler, two motions to exclude the opinions of Prof. Gruber, and two to exclude those of Prof. McGuire.

the Plaintiffs to incur increased costs to address those harms.

1. Prof. Rosenthal: Marketing Caused Increased Sales

Dr. Meredith Rosenthal is a highly-credentialed Professor of Health Economics and Policy at the Harvard T.H. Chan School of Public Health at Harvard University where she teaches undergraduate, masters, and Ph.D.-level health economics and policy courses. She earned her Ph.D. in Health Policy (Economics Track) at Harvard University. She has particular expertise in health care markets and the pharmaceutical industry. As an economist, her research focuses on the financing and organization of the U.S. health care system, including, in particular, the effect of payment incentives on provider behavior, payment and delivery system reform, and advertising and promotion of prescription drugs. She has published more than 150 peer-reviewed journal articles, essays, and book chapters.

For her expert report in this case, Professor Rosenthal assessed and quantified the effect of unlawful manufacturer marketing on increased use of opioids in Summit and Cuyahoga Counties. She offers the opinions that promotion of pharmaceuticals increases sales and that, in particular, unlawful promotion of opioids increased sales of opioids. She also uses economic and econometric modeling to quantify the extent to which increased sales of prescription opioids were caused by Defendants' unlawful marketing. As detailed elsewhere, Professor Rosenthal's opinion is not the only evidence Plaintiffs will offer at trial to show that the Manufacturer Defendants' marketing efforts caused the increased sales of opioids, although her economic analysis provides important confirmation of that causal link. Of significance here, however, Professor Rosenthal's analysis *quantifying* the effect of marketing on sales provides an important input for the analyses performed by Professors Cutler and McGuire linking increased sales to increased harms and increased costs.

2. Professors Gruber and Cutler: Increased Shipments of Opioids Caused Increased Harms

Dr. Jonathan Gruber is a Professor of Economics at the Massachusetts Institute of Technology ("MIT"). He received his Ph.D. in Economics from Harvard University. Like Dr.

Rosenthal, Dr. Gruber is a highly-credentialed economist who specializes in the economics of health and public finance. He has published more than 170 articles and is the author of the leading textbook in the field of public finance. He directs the Health Care Program at the National Bureau of Economic Research, the nation's leading economic think tank. He has been an active participant in the development of health care policy in the United States at both the federal and state levels, serving as an advisor in the developing health care reform in Massachusetts and as a consultant to the Obama administration in the development of the Affordable Care Act. His experience as a health care economist includes extensive work on addictive behaviors, including significant academic research and federal policy experience in the economics of smoking. He has published more than a dozen academic papers on the economics of, and government policy towards, smoking.

In his expert report, Prof. Gruber provides opinions about the origins, unfolding, and scope of the opioid crisis in the United States. Based on his economic analysis, Prof. Gruber concludes that there is a direct causal relationship between shipments of prescription opioids and misuse of and mortality from these drugs. He demonstrates through empirical analysis that geographic areas that received higher *per capita* volumes of shipments of prescription opioids experienced significantly higher *per capita* rates of opioid misuse and mortality. Prof. Gruber also concludes that there is a direct causal relationship between shipments of prescription opioids and misuse and mortality from *illicit* opioids, and he explains the market factors behind the transition from prescription opioids to illicit opioids. Prof. Gruber also concludes that the significant increases in all-opioid mortality are largely unrelated to trends in non-opioid drug overdoses, changes in population demographics, or local economic conditions. He explains how available data indicate that deaths from all opioids grew far more rapidly than non-opioid overdose mortality since the mid-1990s and that opioid mortality trends are similar in areas with different trends in economic activity.

Prof. David Cutler addresses similar issues from a different perspective. Like Prof. Rosenthal,

Prof. Cutler teaches economics at Harvard University, where he has appointments in the Department of Economics, the Harvard Kennedy School, and the Harvard T.H. Chan School of Public Health. He received his Ph.D. in Economics from MIT and, in his academic works, specializes in health economics and public economics. He has published more than 200 articles and has written two books on the economics of health care. He served on the Council of Economic Advisors and the National Economic Council, and has been a Commissioner for the Health Policy Commission in Massachusetts since 2012. As part of its responsibilities, the Commission extensively studied the impact of opioid use on the health of citizens and the cost of medical care in Massachusetts and has sponsored programs to reduce the impact of opioids. Prof. Cutler has published several economics papers on addictive goods, including analyses of smoking, obesity, and other addictive behaviors.

In his expert report, Prof. Cutler analyzed the impact of opioid prescription shipments on harms to Summit and Cuyahoga Counties. His analysis yields annual estimates of harms in each county that are attributable to Defendants' misconduct by utilizing a three-step model which first quantifies the percentages of harms attributable to opioids in the Bellwether Counties, then quantifies the percentage of certain specific harms attributable prescription opioid shipments, and third, quantifies the percentage of these harms attributable to Defendants' misconduct. For this last step of his analysis, Prof. Cutler's model uses Prof. Rosenthal's estimates of the share of prescription opioids attributable to Defendants' unlawful marketing, and estimates from Craig McCann regarding the share of excessive shipments that distributors failed to identify as suspicious.

3. Professor McGuire: Increased Harms Caused Quantifiable Damage to Summit and Cuyahoga Counties

Dr. Thomas McGuire is a Professor of Health Economics in the Department of Health Care Policy at Harvard Medical School, where he teaches health economics in Harvard University's Ph.D. Program in Health Policy. He earned his Ph.D. in economics from Yale University. He is a member of the National Academy of Medicine and a Research Associate at the National Bureau of Economic

Research. For more than 40 years, he has conducted research on the economics of managed care, health insurance, health care payment systems, drug pricing and procurement, the economics of health care disparities by race and ethnicity, and the economics of behavioral healthcare. He has published papers on the economics of drug prices, competition between branded and generic drug products, and insurance coverage for drugs. Prof. McGuire has also conducted research and contributed to public policy specifically regarding behavioral health (mental and addictive illnesses) and co-chaired four conferences on economics and mental health sponsored by the National Institute of Mental Health. He has directly contributed to the design of health insurance and provider payment in behavioral health care.

Prof. McGuire submitted two separate expert reports in this case. In his damages report, Prof. McGuire builds on the work of Professors Rosenthal, Gruber and Cutler to quantify the costs to Summit and Cuyahoga Counties of the harms caused by Defendants' unlawful marketing of opioids. Prof. McGuire analyzes the extent of spending by the Plaintiff Counties attributable to opioid harms, and then uses Prof. Cutler's results to determine the percentage of those costs attributable to Defendants' unlawful conduct. Prof. McGuire is thus able to use economic analysis and the work of Professors Rosenthal, Gruber and Cutler to identify what Summit and Cuyahoga Counties could not identify directly: how much of their spending went to combatting the opioid epidemic, and how much of *that* was caused by Defendants' misconduct, as opposed to drug use not attributable to the Defendants. It is important to understand that, for purposes of Prof. McGuire's analysis, it makes no difference *which* opioid overdoses, *which* babies born with neonatal-abstinence syndrome, *which* opioids orphans requiring social services were the result of Defendants' conduct. The issue is simply how many more there were because of Defendants' misconduct and how this increased the costs of addressing these problems.

Prof. McGuire's other report addresses a different question altogether. In his "public

nuisance" report, Prof. McGuire addresses how the economic concept of "externalities" parallels the legal concept of public nuisance. The economic concept of "externalities" recognizes that, for some activities, profits are reaped by economic actors through the imposition of unrecognized costs on the public at large. It is the imposition of these unrecognized costs, the "externalities," on the public that parallels the concept of public nuisance, an interference with a public right. Prof. McGuire looks at the concept of externalities in the context of the opioid crisis and quantifies the costs imposed by Defendants' conduct on society in Summit and Cuyahoga Counties. This analysis provides an approach to the concept of interference with a public right, quantifying the extent of interference and imposition on the public.[8]

D. Plaintiffs' Abatement Experts: Fixing the Problem

Plaintiffs designated and provided reports for four abatement experts who offer interrelated opinions regarding what must be done to address the opioid epidemic and what it is likely to cost: Dr. Caleb Alexander, Dr. Jeffrey Liebman , Dr. Scott Wexelblatt and Dr. Nancy Young.[9]

1. Dr. Alexander: The Elements of an Effective Abatement Plan

Dr. Caleb Alexander is a practicing general internist and Professor of Epidemiology and Medicine at Johns Hopkins Bloomberg School of Public Health. He received a B.A. from the University of Pennsylvania, an M.D. from Case Western Reserve University, and an M.S. from the University of Chicago. He is also a pharmacoepidemiologist who focuses on the study of the uses and effects of drugs in well-defined populations. For much of the past 8 years, he has devoted most of his professional time addressing the opioid epidemic. He has served as one of three Co-Editors of monographs issued by the Johns Hopkins Bloomberg School of Public Health providing

[8] As part of their "abatement" motion, seeking to exclude the testimony of six experts, Defendants seek to exclude Prof. McGuire's public nuisance report to the extent that Plaintiffs seek to offer it in connection with abatement. That portion of the abatement expert motion is moot with respect to Dr. McGuire, as Plaintiffs do not seek to use the public nuisance report in support of their abatement remedy.

[9] Although not primarily an abatement expert, as discussed above, Dr. Kathrine Keyes also offers opinions that pertain to abatement.

comprehensive, concrete, evidence-based solutions to the epidemic and he has testified before the U.S. House of Representatives regarding the opioid epidemic. He has published extensively about opioids, including analyses of prescription opioid use in the United States as well as evaluations of the structure and impact of regulatory and payment policies on opioid prescribing, dispensing and utilization. He has also coauthored policy perspectives and a widely referenced public health review of the epidemic.

Based on his review and analysis of a wide variety of data sources, Dr. Alexander concludes that an opioid epidemic exists in Summit and Cuyahoga Counties, and he provides an abatement model which includes evidence-based approaches that should be used to reduce opioid related morbidity and mortality. He describes the three major categories of remedies that must be undertaken to address the epidemic: first, improve the safe use of prescription opioids and treatment of pain, since opioid oversupply has been a key driver of the epidemic; second, identify and treat individuals with opioid use disorder; and third, customize abatement remedies for specific subpopulations, including: individuals within the criminal justice system, children, adolescents, and young adults; child in foster care and protective services; pregnant women and neonates; and African Americans, American Indians and Alaskan Natives. Dr. Alexander discusses the costs of implementing these approaches nationally; the cost of implementing them locally in the Bellwether Counties is addressed by Prof. Liebman.

2. Prof. Liebman: An Abatement Plan and an Estimate of Its Cost

Dr. Jeffrey Liebman is Malcolm Wiener Professor of Public Policy at the Harvard Kennedy School, where he directs the Taubman Center for State and Local Government as well as the Government Performance Lab (GPL). He holds a Ph.D. in Economics from Harvard University. He has published numerous peer-reviewed journal articles, essays, and book chapters. He teaches courses on the Economic Analysis of Public Policy, American Economic Policy, and Government Turnarounds. He specializes in Public Finance and Health Economics as well as state and local

government policies. His research focuses on tax, budget, and health policy, impact evaluations of social programs, and strategies for making government social service agencies more effective. From 1998-1999, he was Special Assistant to the President of the United States for Economic Policy and coordinated the National Economic Council's Social Security reform technical working group. From 2009 to 2010, he worked at the Office of Management and Budget ("OMB"), first as Executive Associate Director and Chief Economist and then as Acting Deputy Director. In both periods of government service, he supervised the development of cost estimates of complicated multi-faceted government initiatives, including Social Security reform, the American Recovery and Reinvestment Act of 2009, and the Affordable Care Act of 2010. The GPL, which he founded and directs, provides *pro bono* technical assistance to state and local government agencies, mostly social service agencies, to help them improve the results they achieve for their residents. A significant portion of GPL's nearly 100 projects in more than 30 states has involved substance abuse issues.

In his expert report, Prof. Liebman proposes an abatement plan for the Summit and Cuyahoga communities based on the categories and goals elaborated by Dr. Alexander, and he estimates the cost of implementing the plan over the next 15 years. The abatement plan identifies four major areas of needed services: treatment programs, harm reduction programs, prevention programs, and system coordination efforts. In developing the abatement plan and estimating the funding needed for this plan Prof. Liebman applies the same general methodological framework used in his prior analysis of government programs, in his academic and government work, as well as in the nearly 100 projects that have been implemented under his direction at the GPL. His methodology follows standard approaches used by the Congressional Budget Office, the OMB and the Government Accountability Office in estimating costs and projecting budgets.[10]

[10] Dr. Liebman relies on the opinions of several of Plaintiffs' other experts, including Drs. Alexander, Keyes and Lembke and Profs. Gruber, Cutler and McGuire.

3. Dr. Wexelblatt: Neonatal Abstinence Syndrome and the Elements of an Effective Abatement Plan

Dr. Scott Wexelblatt is Regional Medical Director of Newborn Services at Cincinnati Children's Hospital Medical Center and an Associate Professor in the Department of Pediatrics at the University of Cincinnati College of Medicine. He holds a B.A. degree from the University of Delaware and an M.D. degree from the University of Vermont College of Medicine. He is an expert in Neonatal Abstinence Syndrome ("NAS"). As a faculty member of Ohio Perinatal Quality Collaborative ("OPQC") (a statewide consortium of perinatal clinicians, hospitals, policymakers and governmental entities that aims, through the use of improvement science, to reduce preterm births and to improve perinatal and birth outcomes in Ohio), he has been working with the Ohio Department of Mental Health and Addiction Services ("ODHMAS"), the Ohio Department of Medicaid ("ODM"), and the Ohio Department of Health ("ODH") to improve outcomes for pregnant women with opioid use disorder and their infants. As the regional faculty representative for the Ohio Children's Hospital Association ("OCHA") subcommittee on NAS, he helped establish a protocol for NAS for twenty Ohio children's and maternity hospitals, and the results of the use of that protocol – showing a marked improvement in outcomes – led to the establishment of a standard protocol for NAS.

Dr. Wexelblatt explains how the use and exposure of opioids among pregnant women has increased across the U.S. resulting in a growing incidence of NAS and what has been done to combat the problem. Drawing on, among other things, his experience developing and implementing a protocol that has been effective in combatting NAS, he describes in detail what is required in Summit and Cuyahoga Counties to abate this growing epidemic in their communities.

4. Dr. Young: the Impact of the Opioid Crisis on Child Welfare and the Necessary and Appropriate Remedies

Nancy Young, Ph.D. is a nationally recognized expert in the field of preventing child abuse and neglect, improving safety, permanency, wellbeing, and recovery outcomes for children and families affected by trauma, substance abuse, and mental health disorders. She holds a Bachelor's

degree in Sociology from California State University at Fullerton and a Master of Social Work degree as well as a Ph.D. in Social Work with a concentration in social policy from the University of Southern California, School of Social Work. She is the Executive Director of Children and Family Futures ("CFF"), a research and policy institute whose mission is to improve safety, permanency, well-being and recovery outcomes for children, parents and families affected by trauma, substance use and mental health disorders. Dr. Young is an expert in providing training and technical assistance to states and communities in support of their efforts to enhance cross-systems collaboration for the benefit of this population of families, as well as developing and disseminating information to the field on the advances in policy and practice.

Dr. Young describes the impact of the opioid crisis on child welfare systems and related agencies including recovery courts, and offers her opinion on necessary and appropriate remedies in response to the opioid epidemic. Dr. Young explains how, in the past four decades, major shifts in substance use have dramatically affected children and families, including how the increase in opioid use (and specifically overdose deaths and hospitalizations) has been shown to have a statistical relationship with increased foster care rates and has had other burdensome effects on the child welfare systems of this country. She explains that the current opioid epidemic exhibits at least two major differences from our prior experiences. First, young people are dying at astonishing rates, and second, most states have infants being placed into protective custody at increasingly high rates. Based on knowledge gained from federal, state, and local efforts, and private foundation grant programs over the past decade that have specifically tested strategies to implement evidence-based programs to improve outcomes for families affected by parental opioid and other substance use disorders, Dr. Young is able to recommend practice changes and system reforms to remediate the current opioid crisis.

E. Plaintiffs' Other Experts: Providing Context and Synthesis

Plaintiffs designated and provided reports for four experts, Dr. David Kessler, Dr. David

Egilman, Prof. Matthew Perri, and Prof. David Courtwright,[11] who offer opinions that provide context and synthesis that will assist the trier of fact. The topics covered by these experts include FDA regulatory compliance, the synthesis of voluminous and highly technical evidence, background information concerning pharmaceutical marketing, and historical context.

1. Dr. Kessler: Manufacturers' Departures from FDA Standards

Dr. David Kessler received his M.D. degree from Harvard and his J.D. from the University of Chicago in 1978 and 1979, respectively. He has had special training in pharmacoepidemiology at Johns Hopkins Hospital. He is the former head of the FDA under the administrations of Presidents George H. W. Bush and Bill Clinton. He has taught food and drug law at Columbia University School of Law and has testified many times before the United States Congress on food, drug, and consumer protection issues under federal and state law. He has published numerous articles in legal, medical and scientific journal on the federal regulation of food, drugs, and medical device, including articles on drug promotion and marketing practices and on addiction. In the private sector, he has advised companies on the standards and duties of care in the pharmaceutical and medical device industry.

After reviewing the promotional activities of each Manufacturer Defendant, he concludes that that their departures from FDA standards would be expected to (and likely did) have an effect on how healthcare providers prescribed opioids, contributing to a shift in the practice of medicine with regard to the use of opioids in the treatment of pain. This change in the practice of medicine led to an increase in opioid prescriptions, an increase of opioids in interstate commerce, and an increase in inappropriate use of opioids, all of which in turn increased the risk of opioid abuse and contributed to a public health crisis. In Dr. Kessler's opinion, because the promotional violations discussed in his report are serious, corrective promotion and medical education that disseminates truthful, non-misleading, and complete corrective messaging about the violations discussed above to the audiences that received the

[11] Defendants have not sought to exclude the testimony of Dr. Courtwright.

violative promotion is warranted.

2. Prof. Perri: Explaining Pharmaceutical Marketing

Dr. Matthew Perri is Professor and Associate Head of the Department of Clinical and Administrative Pharmacy at the College of Pharmacy at the University of Georgia. He also serves as the Director of the Pharm D/MBA dual degree program. Originally trained as a pharmacist, Prof. Perri earned a Ph.D with a dual concentration in Pharmacy and Marketing, Prof. Perri teaches graduate and undergraduate courses in health care and pharmaceutical marketing, management, research methods, patient communications, patient care skills laboratories, and biomedical statistics.

Prof. Perri explains what pharmaceutical marketing is, how it differs from other marketing, and what basic standards companies that market prescription opioids should follow. He also examined documents provided by the Defendant and, based on those documents, offers opinions about the Defendants' marketing strategies with respect to prescription opioids, how those strategies were implemented, what Defendants' marketing messages were and how they were disseminated, as well as the effectiveness of Defendants' marketing.

3. Dr. Egilman: Defendants' Concerted Action

Dr. David Egilman is a medical doctor and Clinical Professor of Family Medicine at Brown University. He holds a degree in Medicine from Brown University. Dr. Egilman also completed NIH's three year Epidemiology Training Program, which included epidemiology, statistics, occupational medicine, industrial hygiene, warnings, and occupational and environmental law. As part of that program, he received a Master of Public Health from Harvard University School of Public Health. He served two years at the National Institute for Occupational Safety & Health, where he designed and conducted epidemiologic studies. In the more than 30 years since completing his study at Harvard School of Public Health, Dr. Egilman has become a renowned and recognized expert in numerous areas of medicine. He has published widely on "medical epistemology," the study of cause-and-effect determinations in medicine; on medical ethics; on corporate responsibilities to test products and warn

of health hazards. He has testified (twice) before Congress on proper conduct of medical research including study design and informed consent, corporate responsibility to test products and publish study results, and has published peer reviewed papers on these topics. Dr. Egilman has also published, in peer-reviewed medical journals, on conflicts of interests in the context of public health; techniques used to manipulate scientific studies; post-market safety surveillance; and "guest authorship" and "ghost-writing" in the pharmaceutical industry. His opinions have been admittedby numerous state and federal courts.

Based upon a rigorous and exhaustive review and analysis of medical literature, published books, corporate documents, produced documents, and depositions, Dr. Egilman synthesizes those voluminous and highly technical materials and explains, on a defendant-by-defendant basis, how those materials show that the defendants acted in concert to mislead the public and the medical community about the true nature of opioids.

4. Dr. Courtwright: Historical Development of the Opioid Epidemic

Dr. David Courtwright is a presidential Professor of History at the University of North Florida. He is an internationally recognized authority on the history of drug use and drug policy. Dr. Courtwright provides the historical development of the opioid epidemic from "narcotic conservatism" to the defendants' conduct that sponsored an industry backed campaign which undermined the prevailing belief that the risks of long term use of prescription opioids in treating chronic nonmalignant pain far outweighed the risk of addiction.

Dated: July 31, 2019

Respectfully submitted,

/s/*Paul J. Hanly, Jr.*

Paul J. Hanly, Jr.
SIMMONS HANLY CONROY
112 Madison Avenue, 7th Floor
New York, NY 10016
(212) 784-6400

(212) 213-5949 (fax)
phanly@simmonsfirm.com

/s/ Joseph F. Rice
Joseph F. Rice
MOTLEY RICE
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464
(843) 216-9000
(843) 216-9290 (Fax)
jrice@motleyrice.com

Paul T. Farrell, Jr., Esq.
GREENE KETCHUM, LLP
419 Eleventh Street
Huntington, WV 25701
(304) 525-9115
(800) 479-0053
(304) 529-3284 (Fax)
paul@greeneketchum.com

Plaintiffs' Co-Lead Counsel

/s/ Peter H. Weinberger
Peter H. Weinberger (0022076)
SPANGENBERG SHIBLEY & LIBER
1001 Lakeside Avenue East, Suite 1700
Cleveland, OH 44114
(216) 696-3232
(216) 696-3924 (Fax)
pweinberger@spanglaw.com

Plaintiffs' Liaison Counsel

Hunter J. Shkolnik
NAPOLI SHKOLNIK
360 Lexington Ave., 11th Floor
New York, NY 10017
(212) 397-1000
(646) 843-7603 (Fax)
hunter@napolilaw.com

Counsel for Plaintiff Cuyahoga County, Ohio

Linda Singer
MOTLEY RICE LLC
401 9th St. NW, Suite 1001
Washington, DC 20004
(202) 386-9626 x5626
(202) 386-9622 (Fax)
lsinger@motleyrice.com

Counsel for Plaintiff Summit County, Ohio

On the brief:

Andrea Bierstein
Thomas I. Sheridan III
SIMMONS HANLY CONROY
112 Madison Avenue, 7th Floor
New York, NY 10016